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Generic Duragesic (fentanyl) patches

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Generic *Duragesic* (Fentanyl) Patches

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Background

On January 28, 2005 Mylan Technologies received FDA approval of the abbreviated new drug application (ANDA) for their Fentanyl Transdermal Systems products. Approved were the 25 mcg/hour, 50 mcg/hour, 75 mcg/hour, and 100 mcg/hour products. The FDA deemed these products bioequivalent and therapeutically equivalent to the reference drug, *Duragesic* Transdermal Systems.[1]

Duragesic is manufactured by Alza Corporation and distributed by Janssen Pharmaceutica Products. Alza is also manufacturing a generic fentanyl patch which is identical to *Duragesic* but is distributed by Sandoz and bears the Sandoz generic labeling. It is bioequivalent and therapeutically equivalent to *Duragesic* since it is the same product.

An evaluation of therapeutic equivalence is assigned to pharmaceutical equivalents only if the approved application contains adequate scientific evidence, established through *in vivo* and/or *in vitro* studies, that there is bioequivalence of the product to a selected reference product.[2]

Currently, these two generic fentanyl patches are the only FDA approved products but others are under FDA review. Lavipharm Corp and Endo Pharmaceuticals Inc. have submitted abbreviated new drug applications to the FDA.

Product Differences and Similarities

Mylan's fentanyl transdermal system differs from the Alza-produced *Duragesic* and Sandoz generic patches. Mylan patches are smaller in size compared with the equivalent Duragesic or Sandoz products. The primary difference is the drug reservoir.[3,4]

Mylan uses a solid matrix fentanyl-containing silicone adhesive that is sandwiched between a backing film and protective liner. Just prior to use the protective liner is removed and the rate-controlling fentanyl matrix is applied to the skin.[4]

Duragesic and the Sandoz generic have a liquid fentanyl reservoir. The system consists of an external backing layer, the reservoir of fentanyl and alcohol USP gelled with hydroxyethyl cellulose, an ethylene-vinyl acetate copolymer membrane, a fentanyl-containing silicone adhesive, and a protective liner. This liner is removed prior to application. In this system the ethylene-vinyl copolymer membrane controls the drug delivery rate.[3]

Janssen distributes the only 12.5 mcg/hour product. There are no currently available generic equivalents for this product. It was approved by the FDA in February 2005.

All generic products have the same prescribing information as *Duragesic* in their labels.[3,4]

All used patches contain residual fentanyl in their matrices and should be folded so that the adhesive sides adhere to each other.[3,4] All generic products create the same diversion potential as the brand name.[5]

Based on the average wholesale drug cost, the generic fentanyl patches cost approximately six percent less than *Duragesic* patches.[6]

Commentary

With the availability of generic fentanyl patches, formulary-driven insurance plans and group buying contract decisions may necessitate conversion from the *Duragesic* patch to a generic patch. Because of the FDA AB rating, patch conversion concerns should be minimized.[1]

There have been reports posted on the American Pain Foundation's website describing differences in analgesic efficacy and side effects.[7] Concerns mentioned in postings to their discussion board state that both the Mylan and Sandoz generics are not as effective. Some postings also describe that there are more side effects such as nausea and vomiting with the generic versions.[7]

More. . .

Issues of efficacy may be perceived due to the smaller size of the Mylan patches as compared to the *Duragesic* patches and also the fact that they are generics. Some believe that generics don't work as well as the brand name product. Post-marketing investigation of reports may reveal actual differences. An individual's perception of pain and pain-relief is subjective and must be evaluated with reference to the person's pain control goal. Encourage reporting of product problems. To report product problems, call the FDA MEDWATCH program at 1-800-FDA-1088. The MEDWATCH program is also available on-line at www.fda.gov/medwatch. Or report to the USP Medication Errors Reporting Program in cooperation with the Institute for Safe Medication Practices at 1-800-23-ERROR or at www.usp.org/patientSafety/reporting/mer.html.

Be aware of the potential for actual or perceived differences when switching fentanyl patch products. Patients who have always used the *Duragesic* patch may need to be monitored more closely when switching to a generic patch. During the conversion to a generic patch some patients may require short-acting analgesics for breakthrough pain.

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